201-14331

NCIC HPV
Sent by: Mary-Beth Weaver

03/05/2003 02:24 PM

To: NCIC HPV, Jodi Burgess/DC/USEPA/US@EPA
cc:
cc:
Subject: Environmental Defense comments on Silane,dichloromethyl-, reaction products with silica (CAS 68611-44-9)

Richard_Denison@environmentaldefense.org on 03/04/2003 02:55:38 PM

To: oppt.ncic@epamail.epa.gov, hpv.chemrtk@epamail.epa.gov, Rtk Chem/DC/USEPA/US@EPA, Karen Boswell/DC/USEPA/US@EPA, Stewart_Miller@cabot-corp.com
cc: lucierg@msn.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on Silane,dichloromethyl-, reaction products with silica (CAS 68611-44-9)

(Submitted via Internet 3/4/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and Stewart_Miller@cabot-corp.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Silane,dichloromethyl-, reaction products with silica (CAS 68611-44-9).

This test plan was prepared by a Consortium comprised of Cabot Corporation, Degussa AG and Wacker-Chemie. The substance is formed by coating pyrogenic silica with dimethyldichlorosilane, which renders the molecule hydrophobic. The sponsor says that this substance is exempt from listing under the TSCA Inventory because it is considered an inorganic chemical, although it is coated with an organic molecule.

The sponsor claims that no additional studies are needed on this substance. We disagree with their conclusions for the reasons given below.

The sponsor claims that no environmental fate studies are needed although none are available. However, because the substance does decompose upon wetting, environmental fate studies should be conducted and eco- and mammalian health studies should then be conducted on the decomposition products.

The sponsor claims that all existing repeat dose and reproduction/development studies are flawed because they were conducted using a test substance with a small particle size which permitted the test substance to penetrate deeply into alveolar spaces, where it initiated a wide array of lung lesions and dysfunctions at relatively low doses. The sponsor contends that the commercially available substance has a much larger particle size that would not penetrate into those alveolar spaces, and therefore that it would be non-toxic. The sponsor can't have it both ways. If the existing studies are flawed and not usable for HPV purposes, then they should propose to conduct studies on all health endpoints using an appropriate test substance. If they wish to rely on the existing studies, then they must acknowledge that this substance might pose a health risk to those people exposed to it.

The sponsor states that no health hazards are expected if exposure levels are maintained below the current TLV(10 mg/m3). However, in two separate repeat dose studies, LOAEL's of 31 and 35 mg/m3, respectively, were reported based on lung effects; a NOAEL was not achieved in either study. The common risk assessment practice is to use an uncertainty factor of 10

to extrapolate from a LOAEL to a NOAEL, and to use additional uncertainty factors to account for animal to human extrapolation and for inter-individual variation. Therefore, exposure levels at or below the TLV could cause significant health effects in some people. We are concerned about worker safety for this substance, although our concerns might be diminished to some extent if the sponsor's contention is correct that the existing studies are flawed and if new studies are conducted as we requested in the above paragraph.

Thank you for this opportunity to comment.

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